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Doran R. Pace, Patent Attorney

REQUEST FOR CERTIFICATE OF CORRECTION UNDER 37 CFR 1.322
Docket No. UF-219XC1
Patent No. 6,875,773

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Ben M. Dunn, Janet K. Yamamoto, Maki Arai
Issued	:	April 5, 2005
Patent No.	:	6,875,773
For	:	Combination Therapy for Treatment of FIV Infection

Mail Stop Certificate of Corrections Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CERTIFICATE OF CORRECTION
UNDER 37 CFR 1.322 (OFFICE MISTAKE)

Sir:

A Certificate of Correction (in duplicate) for the above-identified patent has been prepared and is attached hereto.

In the left-hand column below is the column and line number where errors occurred in the patent. In the right-hand column is the page and line number in the application where the correct information appears.

Patent Reads:	**Application Reads:**
Column 2, line 40:	Page 3, line 14:
"FIV-PL"	--FIV-PI--
Column 4, line 31:	Page 6, line 7:
"FIV_{Pet},"	--FIV_{Pet}--

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Column 4, line 31:	Page 6, line 7:
"FIV_{Bang},"	--FIV_{Bang}--
Column 5, line 16:	Page 7, line 9:
"FIV_{Bang},"	--FIV_{Bang}--
Column 5, line 59:	Page 8, line 6:
"Sat 3"	--at 3--
Column 9, line 44:	Amendment dated January 29, 2003 Page 14, line 3:
"P. Schipper, P. Rouse"	-- P. Schipper, R. Schuurman, P. Rouse--
Column 9, line 47:	Amendment dated January 29, 2003 Page 14, line 4:
"2-deoxy-3"	--2′-deoxy-3′--
Column 9, line 48:	Amendment dated January 29, 2003 Page 14, lines 5-6:
"in human"	--of human--
Column 9, line 60:	Amendment dated January 29, 2003 Page 14, line 16:
"preference"	--preferences--
Column 10, line 45:	Amendment dated January 29, 2003 Page 14, line 27:
"*Deflc.*"	--*Defic.*--
Column 10, line 46:	Amendmend dated January 29, 2003 Page 14, line 28:
"10(Suppl. 1):534-540"	--10(Suppl. 1):S34-S40--

Column 10, line 49:	Amendment dated January 29, 2003 Page 14, line 33:
"Hartnaun"	--Hartmann--
Column 10, line 65:	Amendment dated January 29, 2003 Page 15, line 5:
"Johnson, M. C."	--Johnson, C.M.--
Column 11, line 1:	Amendment dated January 29, 2003 Page 15, line 8:
"Lainivudine Working"	--Lamivudine HIV Working--
Column 11, line 8:	Amendment dated January 29, 2003 Page 15, line 13:
"10(Suppl. 1):577-582"	--10(Suppl. 1):S77-S82--
Column 11, line 11:	Amendment dated January 29, 2003 Page 15, line 16:
"10(Suppl. 1):528-533"	--10(Suppl. 1):S28-S33--
Column 11, line 19:	Amendment dated January 29, 2003 Page 15, line 23:
"I L B. Cope"	--R. B. Cope--
Column 11, line 41:	Amendment dated January 29, 2003 Page 16, line 1:
"A. Al. McNamara"	--A. L. McNamara--
Column 11, line 46:	Amendment dated January 29, 2003 Page 16, line 5-6
"a lymphotropic"	--a T-lymphotropic--
Column 11, line 61:	Amendment dated January 29, 2003 Page 16, line 19:
"A. E. M. E. Osterhaus"	--A.D.M.E. Osterhaus--

Column 11, line 66:	Amendment dated January 29, 2003 Page 16, line 23:
"Smith, N.R."	--Smyth, N.R.--
Column 12, line 15:	Amendment dated January 29, 2003 Page 16, line 37:
"90:5663-5666"	--90:5653-5656--
Column 12, line 23:	Amendment dated January 29, 2003 Page 17, line 3:
"protease"	--proteinase--
Column 12, line 34:	Amendment dated January 29, 2003 Page 17, line 12:
"2045-2155"	--204S-215S--.

A true and correct copy of pages 3, 6, 7, and 8 of the specification as filed and a copy of Applicant's Amendment Under 37 CFR §1.111 dated January 29, 2003 which support Applicants' assertion of the errors on the part of the Patent Office accompany this Certificate of Correction.

Approval of the Certificate of Correction is respectfully requested.

Respectfully submitted,

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DRP/gyl

Attachments: Copy of pages 3, 6, 7, and 8 of the specification; Copy of Amendment Under 37 CFR §1.111 dated January 29, 2003

AZT, a nucleoside analog such as 3TC and a retroviral protease inhibitor. In an exemplified embodiment, the protease inhibitor is HBY-793 (Hoescht-Bayer).

Brief Description of the Drawings

Figure 1 shows anti-FIV activities of AZT, 3TC, FIV-PI, and HIV-PI (IDV and SQV) in chronically FIV-infected cell lines. The antiviral activity of the drugs at noncytotoxic doses were evaluated in feline T-cell lines chronically infected with either FIV_{Pet} (subtype A strain) (panel A), or FIV_{Bang} (subtype B strain) (panel B). The RT data are presented as % control, whereby % control represents RT mean of triplicate treated cultures divided by RT mean of triplicate untreated cultures and multiplied by 100. The RT data on harvest days at 6, 9, and 12 are shown. The results from treated culture sets which are statistically different from the values of the untreated controls are indicated by either $p<0.05$ *(P)* or $p<0.005$ (*P**) based on Student T test.

Figure 2 shows anti-FIV activities of AZT, 3TC, FIV-PI, and FIV-PI in primary PBMC infected with FIV_{Bang}. Six separate experiments with varying concentrations and combinations were performed and the results from two representative experiments are shown. Nucleoside analogue and PI doses were 0.1 μM in Experiment 1 (panel A) and 0.05 μM and 0.01 μM, respectively, in Experiment 2 (panel B). The RT data are presented as % control and the results from treated culture sets which are statistically different from the values of the untreated controls are indicated by either $p<0.05$ (*P*) or $p<0.005$ (*P**) based on Student T test. The Harvest Day 16 result for AZT/3TC culture set was statistically different ($p<0.03$) from the results of AZT culture set and 3TC culture set from the same time point, as indicated by (Y) above AZT/3TC bar (panel A). The Day 9 and 12 harvest results for AZT/3TC/FIV-PI culture set were statistically different ($p<0.05$) from the results of AZT/3TC culture set and FIV-PI culture set from the same time points, as indicated by (*Z*) above AZT/3TC/FIV-PI bars (panel B).

Figure 3 shows anti-FIV activities of AZT, 3TC, FIV-PI, and HIV-PI in primary PBMC infected with FIV_{UK-8} (subtype A strain). Four separate experiments with varying concentrations and combinations were performed and the results from two representative experiments are shown. Nucleoside analogue and P1 doses were 0.1 μM and 0.01-0.5 μM, respectively, in Experiment 1 (panel A) and 0.05 μM and 0.01-0.5 μM respectively, in Experiment 2 (panel B). The RT data are presented as % control and the results from

Following are examples which illustrate procedures for practicing the invention. These examples should not be construed as limiting. All percentages are by weight and all solvent mixture proportions are by volume unless otherwise noted.

Example 1 – *In vitro* Efficacy of AZT, 3TC, and PI

In the first set of *in vitro* studies, feline T-cell lines chronically infected with FIV_{Pet} (FL-4 cells) or FIV_{Bang} (FIV_{Bang}/FeT-J cells) at $2x10^5$ cells/ml were treated for 3 weeks with a single drug or various combinations of AZT, 3TC, an FIV protease inhibitor (FIV-PI; Hoescht-Bayer HBY-793), and HIV protease inhibitors (HIV-PI) (Fig. 1A and 1B). Saquinavir (SQV) and Indinavir (IDV) were used as the HIV-PIs. Culture supernatants were harvested and the cells were resuspended in fresh culture media containing appropriate drug(s) at 34 day intervals. Viral replication was determined by measuring the levels of reverse transcriptase (RT) activity in the culture supernatants (Rey *et al.*, 1984). Drug toxicity in these cultures were monitored by viability and absolute cell count analyses using trypan blue exclusion method (Mishell *et al.*, 1980). Single and combination drug doses which were determined to be nontoxic to the test cells were used in these studies.

Both single and combination treatments with AZT and 3TC had minimal to no effect at inhibiting RT activity in FIV_{Bang}/FeT-J cells (20-50% inhibition) and FL-4 cells (0-10% inhibition). In contrast, FIV-PI treatment inhibited FIV replication by 70-80% in both cell lines (Fig. 1A and 1B). However, the addition of an AZT/3TC combination did not enhance this inhibition. Furthermore, neither SQV nor IDV alone had significant anti-FIV effect (Fig. 1A and 1B). The differences in anti-FIV activities of these nucleoside analogues and FIV-PI may be due to the differences in the mechanism(s) of their antiviral activities. AZT and 3TC exert their antiretroviral activity by preventing the reverse transcription of viral RNA into viral DNA, whereas FIV-PI prevents the production of a whole virion by inhibiting the FIV protease from cleaving viral gag-pro--pol precursor into their individual components. Therefore, cell lines which have proviral integration will not be affected by nucleoside analogues. Based on semi-quantitative PCR analysis, FIV_{Bang}/FeT-J cells and FL-4 cells used in current study had proviral integration of 50-80% and >95%, respectively (data not shown). The minor anti-FIV activity of AZT and 3TC observed in FIV_{Bang}/FeT-J cells may be due to the antiviral

effect of the nucleoside analogues on the 20-50% of the cells which were still free of FIV proviral integration. As expected, potent anti-FIV activity was observed with FIV-PI in both proviral integrated cell lines.

As a means to simulate *in vivo* conditions, primary peripheral blood mononuclear cells (PBMC) from specific pathogen free (SPF) cats were next used as the indicator cells. Primary PBMC isolated by ficoll hypaque method were stimulated with concanavalin A for 3 days and cultured for an additional 2 weeks before their use in drug studies (Staszewski, 1995). Antiretroviral drug(s) were added to the PBMC cultures ($1x10^6$ cells/ml) immediately before FIV_{Bang} (subtype B) or FIV_{UK-8} (subtype A) inoculation of 100 50% tissue culture infectious dose ($TCID_{50}$). Both single and combination treatments with AZT and 3TC inhibited the FIV replication in PBMC at doses which were not toxic to the cells (Fig. 2A and 3A). Synergism in antiviral activities of AZT/3TC combination was observed against both FIV_{Bang} and FIV_{UK-8} strains (Fig. 2A, 3A, and 3B). The addition of the FIV-PI to the AZT/3TC combination further enhanced the activities of these drugs against FIV_{Bang} (Fig. 2B). Such enhancement was not observed against FIV_{UK-8} at the doses used (Fig. 3A and 3B). Thus, the anti-FIV activities of AZT, 3TC, and FIV-PI are not restricted to specific FIV strain or subtype, although some strains appear to be more sensitive to one drug over another. Similar to previous studies with chronically infected cells, single-drug treatments with FIV-PI but not HIV-PIs (SQV and IDV) inhibited FIV replication in PBMC cultures (Fig. 2A, 3A, and 3B). Furthermore, addition of SQV or IDV to the AZT/3TC combination did not enhance the antiviral activity of the AZT/3TC combination. The lack of anti-FIV activity of SQV and IDV may be explained by the fact that HIV-PIs do not efficiently bind to FIV protease, whereas the FIV-PI used in this study efficiently binds to HIV protease as well as FIV protease (Dunn *et al.*, 1994; Wlodawer *et al.*, 1995). These results show that dual and triple combinations of AZT, 3TC, and FIV-PI may have therapeutic benefit against FIV infection in domestic cats.

Example 2 – Prophylactic Efficacy of AZT/3TC in Cats

Based on the findings from *in vitro* studies, the prophylactic use of AZT/3TC combination was next tested in experimental cats. Four of the eight SPF cats (16-20 weeks of age) received oral administration of AZT and 3TC (75 mg/kg each) twice a day

(BID), while remaining cats received placebo. This treatment dose was based on the *in vivo* research, in which six SPF cats (2 cats per treatment group) treated (BID) with either AZT or 3TC at 100 mg/kg or AZT/3TC combination at 50 mg/kg each had no hematological or clinical abnormalities after two weeks of treatment. In this study, all cats except for one treated cat (#RUl) were inoculated with 100 50% cat infectious dose ($C1D_{50}$) of FIV_{UK-8} at 3 days after the first drug or placebo treatment. FIV_{UK-8} was used in this study because this strain gave more consistent CD4/CD8 ratio inversion in a larger number of infected cats than did infection with FIV_{Bang} or FIV_{Pet}. All cats received either the drug or placebo treatments throughout the first 11 weeks after FIV inoculation, unless stated otherwise. The cats were monitored daily for clinical signs and twice a month for hematological changes, FIV load in PBMC and plasma, anti-FIV antibody titers, and CD4/CD8 ratio and absolute counts (Diehi *et al.*, 1995; Green *et al.*, 1993; Okada *et al.*, 1994; Tellier *et al.*, 1997; Yamamoto *et al.*, 1991).

At 4 weeks of treatment, severe anemia was observed in all challenged and unchallenged cats treated with AZT/3TC; therefore, the doses of each drug were lowered to 34 mg/kg each at 4 weeks of treatment and subsequently to 5-10 mg/kg each at 5 weeks of treatment. AZT/3TC treatment was terminated in one cat (#3GB) at 6 weeks of treatment, and the treatment was resumed 6 days later at 5 mg/kg each. Based on virus isolation and PCR analyses, one cat (#101) from the placebo group was positive for FIV by 3 weeks post infection (pi) and had anti-FIV antibodies by 5 weeks pi (Table 1). However, plasma viral RNA levels of this cat were not detected throughout the study; even though the virus load in the PBMC was similar to the levels detected in the remaining placebo cats. These placebo cats (#NK4, #NK6, #IH5) were positive for FIV titers in the plasma and PBMC and for anti-FIV antibodies by 7 weeks pi. Furthermore, all placebo cats, except for cat #101, had transient or persistent CD4/CD8 inversion starting 11 weeks pi. In contrast, all AZT/3TC-treated cats were negative for FIV and had no CD4/CD8 inversion throughout the study. Both drug and placebo treatments were terminated at 11 weeks pi and all cats were monitored for additional 6-13 weeks. In the previous reports, an increase in FIV load of the PBMC was observed after the withdrawal of AZT treatment in FIV-infected cats (Hayees, *et al.*, 1993; Hayees *et al.*, 1995; Meers *et al.*, 1993). Thus, if low levels of FIV infection undetectable by current assays existed in AZT/3TC-treated cats, then such infection should rebound when the drugs are

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents Washington, D.C. 20231 on January 29, 2003.

Doran R. Pace, Patent Attorney

AMENDMENT UNDER 37 CFR §1.111
Examining Group 1614
Patent Application
Docket No. UF-219XC1
Serial No. 09/763,037

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner	:	Cybille Delacrois-Muirheid
Art Unit	:	1614
Applicants	:	Ben M. Dunn, Janet K. Yamamoto, Maki Arai
Serial No.	:	09/763,037
Filed	:	February 15, 2001
Conf. No.	:	2654
For	:	Combination Therapy for Treatment of FIV Infection

Assistant Commissioner for Patents
Washington, D.C. 20231

AMENDMENT UNDER 37 CFR §1.111

Sir:

A Petition and Fee for a one-month Extension of Time through and including February 3, 2003, accompanies this Amendment.

In response to the Office Action dated October 2, 2002, please amend the above-identified patent application as follows:

In the Specification

Please replace original pages 14-17 ("References" section) with new pages 14-17 attached hereto.

In the Claims

Please cancel claims 3, 10, and 12-15, without prejudice.

Please substitute the following claims:

Claim 1 (amended):

1. A method for treating or preventing infection of feline immunodeficiency virus (FIV) in a feline animal, said method comprising administering to said feline animal an effective amount of azidothymidine (AZT) and another nucleoside analog, and wherein said feline animal receives bone marrow transplantation after total body irradiation.

Claim 4 (amended):

4. The method according to claim 1, wherein the transplanted cells are selected from the group consisting of allogeneic cells and autologous cells.

Claim 5 (amended):

5. A method for treating or preventing infection of feline immunodeficiency virus (FIV) in a feline animal, said method comprising administering to said feline animal an effective amount of azidothymidine (AZT), another nucleoside analog and an inhibitor of a retroviral protease, and wherein said feline animal receives bone marrow transplantation after total body irradiation.

Claim 8 (amended):

8. The method according to claim 5, wherein said inhibitor of a retroviral protease is designated as HBY-793 and has the structure shown in Figure 4.

Claim 11 (amended):

11. The method according to claim 5, wherein the transplanted cells are selected from the group consisting of allogeneic cells and autologous cells.

Please add the following new claims 16-23:

16. The method according to claim 1, wherein said azidothymidine or said another nucleoside analog is administered as an oral or nasal formulation.

17. The method according to claim 1, wherein said azidothymidine or said nucleoside analog is administered by intravenous, intramuscular, or subcutaneous injection.

18. The method according to claim 1, wherein said azidothymidine or said nucleoside analog is administered in a dosage form selected from the group consisting of tablet, pill, powder, liquid solution or suspension, liposome, suppository, injectable, and infusible solution.

19. The method according to claim 1, wherein said FIV is a strain of FIV selected from the group consisting of FIV_{Pet}, FIV_{Dix}, FIV_{UK-8}, FIV_{Bang}, FIV_{Aom1}, FIV_{Aom2}, and FIV_{Shi}.

20. The method according to claim 5, wherein said azidothymidine, said another nucleoside analog, or said retroviral protease inhibitor is administered as an oral or nasal formulation.

21. The method according to claim 5, wherein said azidothymidine, said another nucleoside analog, or said retroviral protease inhibitor is administered by intravenous, intramuscular, or subcutaneous injection.

22. The method according to claim 5, wherein said azidothymidine, said another nucleoside analog, or said retroviral protease inhibitor is administered in a dosage form selected from the group consisting of tablet, pill, powder, liquid solution or suspension, liposome, suppository, injectable, and infusible solution.

23. The method according to claim 5, wherein said FIV is a strain of FIV selected from the group consisting of FIV_{Pet}, FIV_{Dix}, FIV_{UK-8}, FIV_{Bang}, FIV_{Aom1}, FIV_{Aom2}, and FIV_{Shi}.

Remarks

Claims 1-15 are pending in the subject application. By this Amendment, Applicants have canceled claims 3, 10, and 12-15, amended claims 1, 4, 5, 8, and 11, and added new claims 16-23. Support for the new claims can be found, for example, at page 4, lines 30-31, page 5, lines 19-27, and page 11, lines 10-13, of the subject specification. Entry and consideration of the amendments and new claims presented herein is respectfully requested. Accordingly, claims 1, 2, 4-9, 11, and 16-23 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

The submission of new pages 14-17 is being made to correct inadvertent typographical errors in the References section of the subject application. Entry of the new pages 14-17 in the specification is respectfully requested. Claim 8 has also been amended to correct a typographical error.

As an initial matter, Applicants gratefully acknowledge the Examiner's indication that claims 3, 4, 10, and 11 are objected to but would be allowable if rewritten into independent form to include the limitations of any base and intervening claims.

Claims 1, 2, and 5-9 are rejected under 35 USC §103(a) as obvious over Schinazi *et al.* (WO 96/22778), Hart *et al.* (1995), and Budt *et al.* (1995) in view of Torres *et al.* (1997) and Johnson *et al.* (1994). In addition, claims 12-15 are rejected under 35 USC §103(a) as obvious over Torres *et al.* (1997) in view of Budt *et al.* (1995). The Examiner asserts that the Schinazi *et al.* reference discloses methods for treating FIV using nucleoside analogues, the Hart *et al.* reference teaches methods for treating FIV infected cats by oral administration of AZT, and that the Budt *et al.* reference discloses that the compound HBY-793 is a known HIV protease inhibitor. The Examiner cites the Torres *et al.* reference as disclosing the combined use of AZT, another nucleoside analog (3TC), and a protease inhibitor for treating HIV infection in humans. The Johnson *et al.* reference is cited as teaching that FIV closely resembles HIV in genomic organization, protein composition, and morphology. The Examiner asserts that in view of the references teaching the use of combination therapy to treat HIV, and the similarity between HIV and FIV, it would have been obvious to use the claimed combination therapy to treat FIV infection. Applicants respectfully traverse.

Applicants respectfully assert that the claimed invention is not obvious over the cited references, regardless of whether the references are taken alone or in combination. In particular, Applicants respectfully assert that the use of compounds in humans to treat HIV infection does not necessarily mean that the same compounds will be successful in treating FIV infection in felines. However, in order to expedite prosecution of the subject application, Applicants have amended claim 1 and claim 5 to recite the limitation of claim 3 and claim 10, respectively. Applicants note that claims 3 and 10 were not included under either of the §103 rejections and that the Examiner indicated these claims as containing allowable subject matter. Thus, claims 1 and 5, and those claims dependent therefrom, should be allowable. In addition, Applicants have canceled claims 12-15, thereby rendering the rejection of those claims moot. Accordingly, reconsideration and withdrawal of the rejections under 35 USC §103(a) is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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DRP/sl

Attachments: Marked-Up Version of Amended Claims; New pages 14-17 (References) of the subject specification; Marked-Up Version of References pages.

Marked-Up Version of Amended Claims

Claim 1 (amended):

1. A method for treating or preventing infection of feline immunodeficiency virus (FIV) in a feline animal, said method comprising administering to said feline animal an effective amount of azidothymidine (AZT) and another nucleoside analog, and wherein said feline animal receives bone marrow transplantation after total body irradiation.

Claim 4 (amended):

4. The method according to claim [3] 1, wherein the transplanted cells are selected from the group consisting of allogeneic cells and autologous cells.

Claim 5 (amended):

5. A method for treating or preventing infection of feline immunodeficiency virus (FIV) in a feline animal, said method comprising administering to said feline animal an effective amount of azidothymidine (AZT), another nucleoside analog and an inhibitor of a retroviral protease, and wherein said feline animal receives bone marrow transplantation after total body irradiation.

Claim 8 (amended):

8. The method [accoding] according to claim 5, wherein said inhibitor of a retroviral protease is designated as HBY-793 and has the structure shown in Figure 4.

Claim 11 (amended):

11. The method according to claim [10] 5, wherein the transplanted cells are selected from the group consisting of allogeneic cells and autologous cells.

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DATED : April 5, 2005

INVENTOR : Ben M. Dunn, Janet K. Yamamoto, Maki Arai

It is certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 2,
Line 40, "FIV-PL" should read --FIV-PI--.

Column 4,
Line 31, "FIV_{Pet}," should read --FIV_{Pet}--.
Line 31, "FIV_{Bang}," should read --FIV_{Bang}--.

Column 5,
Line 16, "FIV_{Bang}," should read --FIV_{Bang}--.
Line 59, "Sat 3" should read --at 3--.

Column 9,
Line 44, "P. Schipper, P. Rouse" should read --P. Schipper, R. Schuurman, P. Rouse--.
Line 47, "2-deoxy-3" should read --2′-deoxy-3′--.
Line 48, "in human" should read --of human--.
Line 60, "preference" should read --preferences--.

Column 10,
Line 45, "*Deflc.*" should read --*Defic.*--.
Line 46, "10(Suppl. 1):534-540" should read --10(Suppl. 1):S34-S40--.
Line 49, "Hartnaun" should read--Hartmann--.
Line 65, "Johnson, M. C." should read --Johnson, C.M.--.

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